

AMENDMENTS TO THE CLAIMS

Applicants respectfully request that this Listing of Claims replace all prior versions and listings of claims in this application:

Listing of Claims

1.-177. (canceled)

178. (currently amended) A solid oral dosage form which is effective in delivering a drug and an enhancer, each as defined below, to epithelial cells lining an intestine and which comprises a pharmaceutical composition consisting essentially of comprising:

(1) a compressible blend of

(A) about 0.5 µg to about 1000 mg a therapeutically effective amount of a hydrophilic or macromolecular drug which: (i) is present in a therapeutically effective amount; (ii) is in the form of crystalline and/or amorphous particles, in admixture with and (iii) is hydrophilic or macromolecular; and

(B) an absorption enhancer which: (i) is a solid at room temperature; (ii) is a salt of a medium chain fatty acid having a carbon chain length of from 8 to 14 carbon atoms in particulate form and is the only enhancer present in the composition; and (iii) is present in the dosage form in a therapeutically effective amount and such that the ratio of the drug to the enhancer is 1:100,000 to 10:1, and

(2) a delayed release polymer coating,

wherein and such that the enhancer the salt of the medium chain fatty acid is the only component of the dosage form that enhances intestinal delivery absorption of the drug to the underlying circulation across said epithelial cell lining.

179.-181. (Canceled)

182. (currently amended) A solid oral dosage form according to claim 178 ~~180~~ wherein ~~the composition includes:~~

(A) ~~a~~ the drug is selected from the group consisting of peptides, proteins, oligosaccharides, polysaccharides, and hormones; and

(B) ~~an~~ the absorption enhancer is selected from the group consisting of sodium caprate, sodium caprylate, and sodium laurate.

183. (currently amended) A solid oral dosage form according to claim ~~180~~ which includes 182, wherein the drug is an anticoagulant drug and an enhancer selected from the group consisting of sodium caprate, sodium caprylate, and sodium laurate.

184. (currently amended) A solid oral dosage form according to claim 183, wherein the anticoagulant ~~drug~~ is selected from the group consisting of heparin, low molecular weight ~~heparins~~ heparin, heparanoids, hirudin, and analogues of the foregoing.

185. (currently amended) A solid oral dosage form according to claim 184, wherein the anticoagulant is including heparin.

186. (currently amended) A solid oral dosage form according to claim 184, wherein the anticoagulant drug is including low molecular weight heparin.

187. (currently amended) A solid oral dosage form according to claim 185, wherein the absorption enhancer is sodium caprate ~~and the ratio of the heparin to the sodium caprate is 1:1000 to 10:1.~~

188. (currently amended) A solid oral dosage form according to claim 186, wherein the absorption enhancer is sodium caprate ~~and the ratio of the low molecular heparin to the sodium caprate is 1:1000 to 10:1.~~

189. (withdrawn) A form according to claim 180 wherein the composition includes a bisphosphonate.

190. (withdrawn) A form according to claim 189 wherein the bisphosphonate is alendronate.

191. (withdrawn) A form according to claim 189 wherein the bisphosphonate is etidronate.

192. (withdrawn) A form according to claim 190 wherein the enhancer is sodium caprate and the ratio of the alendronate to the sodium caprate is 1:1000 to 10:1.

193. (withdrawn) A form according to claim 182 wherein the composition includes a peptide drug.

194. (withdrawn) A form according to claim 182 wherein the composition includes a protein drug.

195. (withdrawn) A form according to claim 182 wherein the composition includes an oligosaccharide drug.

196. (currently amended) A solid oral dosage form according to claim 182, wherein ~~the composition includes the drug~~ is a polysaccharide drug.

197. (withdrawn) A form according to claim 182 wherein the composition includes a hormone drug.

198. (currently amended) A solid oral dosage form according to claim 178, wherein the absorption enhancer is sodium caprate.

199.-201. (canceled)

202. (currently amended) A solid oral dosage form according to claim ~~201~~ 178, wherein the ~~polymeric material~~ delayed release polymer is hydroxypropyl-methylcellulose.

203. (currently amended) A solid oral dosage form according to claim ~~480~~ 178, wherein the ~~enteric-coated tablet~~ solid oral dosage form is an ~~instant release tablet~~ a rapid onset dosage form.

204. (currently amended) A solid oral dosage form according to claim ~~480~~ 178, wherein the delayed release polymer ~~enteric coating comprises a polymer~~ is selected from the group consisting of poly(acrylic acid), polyacrylate, poly(methacrylic acid) and polymethacrylate, and mixtures thereof.

205. (currently amended) A solid oral dosage form according to claim 178, wherein ~~the composition~~ said compressible blend is ~~a multiparticulate~~ encapsulated.

206. (currently amended) A solid oral dosage form according to claim ~~205~~ 178, wherein ~~the multiparticulate~~ said compressible blend is ~~in~~ directly compressed into the form of a tablet.

207. (withdrawn) A form according to claim 199 wherein the drug is a bisphosphonate.

208. (currently amended) A solid oral dosage form according to claim ~~499~~ 198, wherein the drug is heparin.

209. (currently amended) A solid oral dosage form according to claim ~~499~~ 198, wherein the drug is a low molecular weight heparin.

210. (currently amended) A solid oral dosage form according to claim 178, wherein the absorption enhancer is a combination of at least two medium chain fatty acid salts each having a carbon chain length of from 8 to 14 carbon atoms, ~~wherein said~~ and the combination ~~enhances enhancer present in the composition of medium chain fatty acid~~ salts is the only component of the dosage form that enhances absorption of the drug.

211. (currently amended) A compressible composition ~~which is capable of being~~ compressed into a solid oral pharmaceutical dosage form which is effective in delivering therapeutically effective amounts of a drug and an enhancer, as defined below, to epithelial cells lining an intestine, said composition ~~consisting essentially of comprising:~~

a compressible blend of

(A) a therapeutically effective amount of a hydrophilic or macromolecular drug which is: (i) in the form of crystalline or amorphous particles, in admixture with and (ii) ~~hydrophilic or macromolecular; and~~

(B) an absorption enhancer which: (i) is a solid at room temperature; (ii) is a salt of a medium chain fatty acid having a carbon chain length of from 8 to 14 carbon atoms in particulate form ~~and is the only enhancer present in the composition; and~~ (iii) is present in the dosage form in a therapeutically effective amount and such that the ratio of the drug to the enhancer is 1:100,000 to 10:1,

~~wherein and such that the enhancer~~ the salt of the medium chain fatty acid is the only component of the dosage form that enhances absorption intestinal delivery of the drug ~~to the underlying circulation across said epithelial cell lining.~~

212. (currently amended) A compressible composition according to Claim 211, wherein the compressible blend is in the form of a compressible powder or of compressible granules granulation.

213. (currently amended) A compressible composition according to Claim 211 further comprising a delayed release polymer including a rate-controlling polymeric material.

214. (currently amended) A compressible composition according to Claim 212 further comprising a delayed release polymer including a rate-controlling polymeric material.

215.-221. (canceled)

222. (currently amended) A compressible composition according to claim 211, wherein which includes:

(A) a the drug is selected from the group consisting of peptides, proteins, oligosaccharides, polysaccharides, and hormones; and

(B) ~~an~~ the absorption enhancer is selected from the group consisting of sodium caprate, sodium caprylate, and sodium laurate.

223. (currently amended) A compressible composition according to claim 211, wherein the drug is which includes an anticoagulant drug and the absorption an enhancer is selected from the group consisting of sodium caprate, sodium caprylate, and sodium laurate.

224. (currently amended) A compressible composition according to claim 223 wherein the anticoagulant ~~drug~~ is selected from the group consisting of heparin, low molecular weight heparin, heparanoid, hirudin, and analogues thereof.

225. (currently amended) A compressible composition according to claim 224, wherein the anticoagulant is including heparin.

226. (currently amended) A compressible composition according to claim 224, wherein the anticoagulant is including low molecular weight heparin.

227. (currently amended) A compressible composition according to claim 225 wherein the absorption enhancer is sodium caprate ~~and the ratio of the heparin to the sodium caprate is 1:1,000 to 10:1.~~

228. (currently amended) A compressible composition according to claim 226 wherein the absorption enhancer is sodium caprate ~~and the ratio of the low molecular weight heparin to the sodium caprate is 1:1000 to 10:1.~~

229. (withdrawn) A composition according to claim 211 including a bisphosphonate and an enhancer selected from the group consisting of sodium caprate, sodium caprylate, and sodium laurate.

230. (withdrawn) A composition according to claim 229 wherein the bisphosphonate is alendronate.

231. (withdrawn) A composition according to claim 229 wherein the bisphosphonate is etidronate.

232. (withdrawn) A composition according to claim 230 wherein the absorption enhancer is sodium caprate and the ratio of alendronate to sodium caprate is 1:1000 to 10:1.

233. (withdrawn) A composition according to claim 222 including a peptide drug.

234. (withdrawn) A composition according to claim 222 including a protein drug.

235. (withdrawn) A composition according to claim 222 including an oligosaccharide drug.

236. (currently amended) A compressible composition according to claim 222, wherein ~~including the drug is~~ a polysaccharide ~~drug~~.

237. (withdrawn) A composition according to claim 222 including a hormone drug.

238. (currently amended) A compressible composition according to claim 211, wherein the absorption enhancer is sodium caprate.

239. (currently amended) A composition according to claim 211, wherein the absorption enhancer is a combination of two or more medium chain fatty acid salts each having a carbon chain length of from 8 to 14 carbon atoms, wherein said ~~and the~~ combination is ~~the only enhancer present in the composition and enhances enhancer present in the composition~~ of said two or more medium chain fatty acid salts is the only component of the composition that enhances absorption of the drug.

240. (currently amended) A solid oral dosage form which is effective in delivering a drug and an enhancer, each as defined below, to epithelial cells lining an intestine ~~and which comprises an enterically coated pharmaceutical composition consisting essentially of comprising:~~

(1) a compressible blend of

(A) ~~about 0.5 µg to about 1000 mg~~ a therapeutically effective amount of a hydrophilic or macromolecular drug which: (i) is present in a therapeutically effective amount; (ii) is in the form of crystalline or amorphous particles; and (iii) wherein the drug is selected from the group consisting peptides, proteins, oligosaccharides, polysaccharides, hormones, bisphosphonates, and anti-coagulants, in admixture with; and

(B) sodium caprate which: (i) is in particulate form; the only enhancer present in the composition; and (ii) is present in the dosage form in a therapeutically effective amount and such that the ratio of the drug to the enhancer is 1:1,000 to 10:1, and

(2) a delayed release polymer coating,

~~and such that the enhancer wherein the sodium caprate is the only component of the dosage form that enhances intestinal delivery~~ absorption of the drug to the underlying circulation across said epithelial cell lining.

241. (withdrawn) A form according to claim 240 wherein the drug is a peptide.

242. (withdrawn) A form according to claim 240 wherein the drug is a bisphosphonate.

243. (withdrawn) A form according to claim 240 wherein the drug is alendronate.

244. (currently amended) A solid oral dosage form according to claim 240, wherein the drug is an anti-coagulant.

245. (currently amended) A solid oral dosage form according to claim 240, wherein the drug is low molecular weight heparin.

246. (currently amended) A compressible composition ~~which is capable of being compressed into a solid oral pharmaceutical dosage form~~ which is effective in delivering therapeutically effective amounts of a drug and an enhancer, as defined below, to epithelial cells lining an intestine, said composition consisting essentially of comprising: a compressible blend of

(A) a therapeutically effective amount of a hydrophilic or macromolecular drug ~~which is: (i) in the form of~~ crystalline or amorphous ~~particles; and (ii) wherein the drug~~ is selected from the group consisting of peptides, proteins, oligosaccharides, polysaccharides, hormones, bisphosphonates, and anti-coagulants, ~~in admixture with; and~~

(B) sodium caprate which: (i) is in particulate form; the only enhancer present in the composition; and (ii) is present in the composition in a therapeutically effective amount and such that the ratio of the drug to the enhancer is 1:1,000 to 10:1, and

~~and such that the enhancer wherein the sodium caprate is the only component of the dosage form that~~ enhances intestinal delivery absorption of the drug ~~to the underlying circulation across said epithelial cell lining.~~

247. (withdrawn) The composition of claim 246, wherein the drug is a peptide.

248. (withdrawn) The composition of claim 246, wherein the drug is a bisphosphonate.

249. (withdrawn) The composition of claim 246, wherein the bisphosphonate is alendronate.

250. (currently amended) The compressible composition of claim 246, wherein the drug is an anti-coagulant.

251. (currently amended) The compressible composition of claim 246, wherein the drug is low molecular weight heparin.

252. (withdrawn) A process for the manufacture of a composition which is capable of being compressed into a solid oral dosage form which is effective in delivering therapeutically effective amounts of a drug and an enhancer, as defined below, to the intestine, the process comprising the steps of:

(A) providing compressible constituents consisting essentially of:

(1) a drug which: (i) is present in a therapeutically effective amount; (ii) is crystalline or amorphous; and (iii) is hydrophilic or macromolecular; and

2) an enhancer which: (i) is a solid at room temperature; (ii) is a salt of a medium chain fatty acid having a carbon chain length of from 8 to 14 carbon atoms and is the only enhancer present in the composition; (iii) is present in a therapeutically effective amount and such that the ratio of the drug to the enhancer is 1:100,000 to 10:1 and such that the enhancer enhances intestinal delivery of the drug to the underlying circulation; and

(B) combining the constituent to form a compressible powder or compressible granules.

253. (currently amended) A solid oral dosage form according to Claim 178, wherein each component of said ~~constituents~~ compressible blend, and any other ~~constituent~~ component of the dosage form, comprising the composition is a solid at room temperature.

254. (currently amended) A compressible composition according to Claim 211,
wherein each component of said ~~constituents~~ compressible blend, and any other
~~constituent~~ component of the compressible composition, is a solid at room temperature.

255. (currently amended) A solid oral dosage form according to Claim 240, wherein
each component of said ~~constituents~~ compressible blend, and any other ~~constituent~~
component of the dosage form, comprising the composition is a solid at room
temperature.

256. (currently amended) A compressible composition according to Claim 246,
wherein each component of said ~~constituents~~ compressible blend, and any other
~~constituent~~ component of the compressible composition, is a solid at room temperature.

257. (withdrawn) A process according to Claim 252 wherein each of said constituents
and any other constituent comprising the composition is a solid at room temperature.